JAN 13 2006

K052935

510(k) Summary of Safety and Effectiveness

Manufacturer and Submitter

Company Name:	Heidelberg Engineering GmbH
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Contact Person:	Dr. Gerhard Zinser
Date Summary Prepared:	August 15, 2004

Device

Trade/Device Name:	SL-OCT
Common/Usual Name:	Slitlamp Optical Coherence Tomography
Classification Name:	AC-powered Slit-Lamp Biomicroscope
Regulation Number:	21 CR 886.1850
Product Code:	MXK
Classification Panel:	Ophthalmic
Classification:	Class II device

Substantial Equivalence

The SL-OCT is substantially equivalent to the Haag Streit AG Optical Low Coherence Pachymeter Pachy-01 SL

Device Description

The SL-OCT enables non-destructive in-depth measurements of the structure and/or form of the anterior segment of the human eye. The visible structures are distinguished on the basis of their varying optical characteristics at the light wavelength used.
The information can be displayed, analysed and documented by the SL-OCT. To this end, a pre-installed software package – which may only be operated on this system – is supplied with the examination system.
This software records and displays the data and controls the measurement process. In addition, the software allows subsequent editing and saving of data to a database. The database provides no permanent and secure archiving of OCT measurement data. For the documentation, the data are printed out and attached to the patient's medical record.
The images provided by the SL-OCT allow qualitative statements to be made about the dimensions and structures of the anterior segment and the dimensions of the identified structures to be quantified.
The SL-OCT is particularly suitable for non-contact in vivo imaging of the cornea, the chamber angle and the anterior chamber.

Intended Use

The SL-OCT is intended as an aid for the quantitative analysis of structures and the diagnosis and assessment of structural changes in the anterior segment of the eye.
The SL-OCT examination system is not intended for the analysis of the cross-sectional images to obtain quantitative measured values. Neither the obtained measured values nor the qualitative evaluation of the images should be used as the sole basis for therapy-related decisions.

Technological Characteristics Compared to Predicate Device

Comparison of similarities and differences:

Comparison items	**SL-OCT**	**Optical Low Coherence Pachymeter**
k number	-	K030393
Indications for use	Imaging and observation of the anterior segment of the eye for diagnostic purposes.	Biometric diagnose of the anterior segment of the eye.
Corneal contact	No	No
Working distance cornea to objective	Ca. 50 mm	ca. 50 mm
Corneal contact sensing and warning feature	Not applicable.	Not applicable.
Pre-sterilized contact surface	Not applicable.	Not applicable.
Front surface area	Not applicable	Not applicable.
Focus	Not applicable	Not applicable.
Focus adjustment range	Not applicable	Not applicable.
Adjustment direction	Device is adjusted horizontally while the patient is sitting straight in front of the device.	Device is adjusted horizontally while the patient is sitting straight in front of the device.
Working position	Horizontal	Horizontal
Optical setup	Conventional microscope	Conventional microscope.
Type of scanning aperture	Point.	Point.
Scanning means	Resonant and galvanometric scanning motor.	Rotating mirror.
Light source	SLD 1310nm Laser Class 1	Laser Light in the visible infrared spectral regions
Microscope lens	Not applicable	Not applicable.
Lateral optical resolution	20 µm - 100 µm	ca. 10 microns
Optical depth resolution	Axial optical resolution capacity: <25 µm	ca. 1 micron
Detector	InGaAs - photodiode.	Si-Photodiode
Lateral field of view	Up to 15 mm	Up to 15 mm.
Lateral digital resolution	20 µm - 100 µm	
Digital depth resolution	Axial digitalized resolution capac-	

Comparison items	SL-OCT	Optical Low Coherence Pachymeter
	ity: 4 µm	
Image acquisition time	1s	Not applicable.
Acquisition of three-dimensional images	No	No
Microscope lens magnification	Ca. 16x	ca. 16x
Magnification on screen (15", 1024x768 pixels)	300x	ca. 100x
Image storage	Directly into PC RAM, then to PC hard drive.	Not applicable.
Image compression method	Not applicable	Not applicable.
Corneal profile measurement	Yes	Cornea thickness measurement.
Operating and image management software	Custom	Not applicable.
Physical layout	Lift table, mount with headrest, optical head are separate components.	Lift table, mount with headrest, optical head are separate components.

Conclusions from Performance Testing

The SL-OCT has been tested according to IEC 60601-1 and IEC 60601-1-2, and was found to meet all requirements. The system is a laser product of Class 1 according to 21 CFR Part 1040 Section 1040.10 and IEC 60825-1:1993+A2:2001.
The evaluation of the device and comparison of acquired images resulted in substantial equivalence to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2007

Heidelberg Engineering GmbH
c/o Mr. Jeffrey D. Rongero
Project Engineer
Underwriters Laboratories, Inc
12 Laboratory Drive
Research Triangle, NC 27709

Re: K052935
Trade/Device Name: Heidelberg Retina Slitlamp-OCT (SL-OCT)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-powered
Regulatory Class: II
Product Code: OBO
Dated: January 4, 2006
Received: January 10, 2006

Dear Mr. Rongero:

This letter updates our substantially equivalent letter of January 13, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Evenette M Beers PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HEIDELBERG ENGINEERING

Indication for Use

510(k) Number (if known): K052935

Device Name: SL-OCT

Indication for Use: The SL OCT is an add on for a slit lamp biomicroscope and is intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. It is used for diagnostic purposes.

Prescription Use ____X____ and / or Over-The –Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K052935

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)